

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

STERIGENICS U.S., LLC,

Plaintiff,

v.

**JOHN KIM, not individually, but solely in
his capacity as Acting Director of the Illinois
Environmental Protection Agency, and the
ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY,**

Defendants.

Case No.

COMPLAINT

COMES NOW plaintiff Sterigenics U.S., LLC (“Sterigenics”), and states as follows:

INTRODUCTION

1. On Friday, February 15, 2019, defendant the Illinois Environmental Protection Agency (“IEPA”) issued a “Seal Order” that sealed “[a]ll storage containers of ethylene oxide” at Sterigenics’ sterilization facility in Willowbrook, Illinois (the “Willowbrook facility”). The Seal Order was signed by defendant John Kim, Acting Director of the IEPA (“Kim”).

2. The Seal Order was purportedly issued pursuant to 415 ILCS 5/34(b), a statute that applies only if “an emergency condition exists” or if there is “imminent and substantial endangerment to the public health or welfare or the environment.” Neither of these conditions exists at the Willowbrook facility. To the contrary, as the Seal Order reflects, and defendants cannot dispute, the Willowbrook facility is operating in full compliance with the operating permits issued by the IEPA, and all relevant and applicable regulations.

3. By entering the Seal Order, defendants seek to circumvent both regulatory and judicial processes to which Sterigenics is entitled by reason of its permits and lawful operations, effectively shutting down the Willowbrook facility by preventing the use of ethylene oxide. To be clear, as IEPA has recognized, the operations that the Seal Order effectively shuts down have been *expressly authorized by IEPA* pursuant to the operating permits issued by that very agency, and which remain in full force and effect. The IEPA has taken no action to revoke, alter, modify, or terminate the operating permits it issued to Sterigenics. Instead, it has summarily issued a Seal Order in an extra-legal attempt to accomplish instantaneously what it cannot lawfully do without proper notice and judicial process. The Seal Order violates the due process requirements of the federal Constitution, does not comply with the requirements set forth in the Illinois Environmental Protection Act, and is inconsistent with governing federal and Illinois law and regulations pertaining to ethylene oxide.

4. By this action, Sterigenics seeks temporary, preliminary and permanent injunctive relief barring IEPA and John Kim from attempting to enforce the unlawful Seal Order.

PARTIES, JURISDICTION & VENUE

5. Plaintiff Sterigenics is a sterilization company with its principal place of business in Broadview Heights. Sterigenics is a leading provider of state-of-the-art commercial sterilization services for the healthcare and food industries. Sterigenics operates the Willowbrook facility, which conducts ethylene oxide sterilization of medical devices, surgical kits, and other medical equipment. On a typical day, the Willowbrook facility sterilizes approximately 200 pallets of medical products, which contain approximately 1,000 cardiac devices used in heart surgery, 1,000 knee implants, 1,500 surgical procedure kits, 16,000

catheters, 11,000 syringes used in radiology diagnosis, and thousands of diabetes monitoring and care kits, renal care products, neurological devices, and respiratory care products.

6. Defendant Kim is the Acting Director of IEPA.

7. Defendant IEPA is an agency of the State of Illinois.

8. This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1367. Count I, brought under 42 U.S.C. § 1983, contends that Defendants Kim and IEPA have, by issuing the Seal Order, violated Sterigenics' rights under the Due Process Clause of the Fourteenth Amendment to the Constitution of the United States.

9. This Court has personal jurisdiction over IEPA and Kim because they are residents of Illinois.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because IEPA and Kim are subject to personal jurisdiction in this Judicial District and because the events giving rise to Sterigenics' claims occurred in Willowbrook, Illinois, which is within this Judicial District.

FACTUAL BACKGROUND

11. Sterigenics or its predecessors have operated an ethylene oxide sterilization facility in Willowbrook, Illinois, since 1984.

12. All aspects of the Willowbrook facility's emissions are subject to environmental regulation. The Willowbrook facility operates pursuant to permit No. 95120085 issued by IEPA under the United States Environmental Protection Agency's Clean Air Act Permit Program ("CAAPP"), which governs how much ethylene oxide can be used and emitted annually.

13. The Willowbrook facility has been operating pursuant to IEPA-issued permits since its doors opened in 1984. On January 30, 2006, IEPA issued modified CAAPP Permit No.

95120085 to Sterigenics for the Willowbrook facility and on June 8, 2015, IEPA renewed CAAPP permit No. 95120085. On June 26, 2018, IEPA issued Permit No. 18060020 to duct the emissions of EO from the backvent valves to existing pollution control devices.

14. The Willowbrook facility is not in violation of any rules or regulations promulgated by the United States Environmental Protection Agency (“USEPA”) or IEPA.

15. Neither the IEPA nor USEPA have modified, revoked or terminated the current lawful permit Nos. 95120085 or 18060020.

16. On October 30, 2018, a lawsuit was filed by the Attorney General of Illinois and the State’s Attorney for DuPage County (“IAG Action”) against Sterigenics. On December 5, 2018, Sterigenics timely removed the IAG Action to this Court based on federal question jurisdiction. *See People of the State of Illinois et al. v. Sterigenics U.S., LLC*, No. 2018cv08010 (N.D. Ill.; IAG Action Dkt. 1.) The IAG Action, which is currently pending before Judge Lee, is related to, and seeks essentially the same relief as the Seal Order. Indeed, the IAG Action asserts a Count for “Causing, Threatening or Allowing Air Pollution,” and alleges that this Count was advanced at the request of IEPA. (IAG Action Dkt. 1-1 at PageID 90.) That Count asks the Court “to enter a preliminary and, after trial, permanent injunction,” specifically requesting that the Court “order[] [Sterigenics] to cease operations if warranted, or setting [ethylene oxide] limits on the [Willowbrook facility] so as to ensure the protection of public health and the elimination of the threat of air pollution to the surrounding community.” (IAG Action Dkt. 1-1 at PageID 104.) Notably, however, none of the relief requested in the IAG Action was sought on an emergency basis, nor did the IAG Action characterize the conditions involving the Willowbrook facility as posing an “imminent and substantial endangerment to the public health or welfare or the environment.” *Cf.*, 415 ILCS 5/34(b)

17. On January 3, 2018, plaintiff in the IAG Action filed a motion to remand the IAG Action back to state court. (IAG Action Dkt. 28.) Sterigenics filed its memorandum in opposition to the motion to remand on January 25, 2019. (IAG Action Dkt. 35.) Plaintiff in the IAG Action filed its reply in support of its motion to remand on February 8, 2019 (IAG Action Dkt. 36), and filed a motion to expedite the ruling on the motion to remand that same day (IAG Action Dkt. 39). Sterigenics filed a response to the motion to expedite on February 11, 2019 (IAG Action Dkt. 41) and on February 13, 2019, plaintiff in the IAG Action filed a reply in support of the motion to expedite (IAG Action Dkt. 42).

18. The Court entered a minute order in the IAG Action on February 13, 2019, acknowledging “the concerns expressed by the parties” and stating it would “issue a ruling on the motion for remand as soon as practicable.” (IAG Action Dkt. 43.) On February 15, 2019, the Court entered a minute order in the IAG Action requesting supplemental briefing to “address whether the doctrine of complete preemption applies and, if so, the effect of the doctrine on this case.” (IAG Action Dkt. 44.)

19. On February 15, 2019, at approximately 5:00 pm, Kim and IEPA issued a Seal Order sealing “[a]ll storage containers of ethylene oxide” at the Willowbrook facility. The Seal Order was purportedly issued pursuant to Section 34(b) of the Illinois Environmental Protection Act. The purported findings in the Seal Order are almost identical to the statements made in plaintiff’s Complaint in the IAG Action.

20. In claiming that an emergency exists, the Seal Order cites an August 2018 report issued the Agency for Toxic Substances and Disease Registry (“ATSDR”). USEPA and ATSDR

have publicly acknowledged, however, that the ATSDR report cited in the Seal Order did not indicate an immediate health threat or emergency situation.¹

21. Both the ASTDR report and the USEPA Integrated Risk Information System (“IRIS”) assessment cited in the Seal Order, upon which the Seal Order relied, are deeply flawed, and Sterigenics disputes their accuracy and validity.

22. USEPA has acknowledged that it “remains premature to draw conclusions about long-term health risks from” its ambient air sampling near the Willowbrook facility.

23. At all relevant times, Sterigenics has operated and continues to operate the Willowbrook facility in compliance with applicable operating permits issued by the IEPA, and which remain in full force and effect under the CAAPP program, and with federal and state regulations concerning emissions of ethylene oxide.

COUNT I
Deprivation of Due Process – 42 U.S.C. § 1983

24. Sterigenics hereby incorporates Paragraphs 1–23 of this Complaint as if fully set forth herein.

25. The Seal Order does not satisfy procedural due process requirements. The Due Process Clause of the Fourteenth Amendment to the United States Constitution “imposes constraints on governmental decisions which deprive individuals of ‘liberty’ or ‘property’ interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.” *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

26. There can be no doubt that Sterigenics holds a fundamental property interest in the benefit of operating the Willowbrook facility in the manner that IEPA itself has licensed. Even if Sterigenics succeeds in getting the Seal Order lifted at some uncertain point in the future,

¹ See IAG Action, Dkt. 1-6; *id.* Dkt. 1-5 at 0:42.

both Sterigenics and its customers will be irreparably harmed through even a temporary loss of the benefit of using its facility—in a manner expressly authorized by IEPA—during the intervening period.

27. In light of this compelling constitutional interest, the complete lack of process afforded Sterigenics is entirely inadequate to afford it the notice and hearing required to ensure procedural due process. Indeed, the “[t]he fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner.” *Mathews*, 424 U.S. at 333. First, Sterigenics has been denied adequate notice of the nature and factual grounds of the Seal Order. The Seal Order seals “[a]ll storage containers of ethylene oxide” purportedly pursuant to Section 34(b) of the Illinois Environmental Protection Act. Section 34(b) applies in situations where “an emergency condition exists” or if there is “imminent and substantial endangerment to the public health or welfare or the environment.” Nowhere in the Seal Order does it explain how the “storage containers of ethylene oxide” are causing an “emergency condition” or “imminent and substantial endangerment.” Second, the Seal Order improperly circumvents the regulatory process. The Willowbrook facility operates *pursuant to express authorizations issued by the IEPA in the form of lawful permits that remain in full force and effect*. If IEPA wants to alter those authorization and regulations, it should seek to implement what it deems to be appropriate emissions standards through the CAAPP permit IEPA itself issued, or initiate rule-making or legislative activity to change emissions standards and regulations, as it is authorized to do through the Clean Air Act, 42 U.S.C. § 7401, *et seq.*

28. In fact, even though Sterigenics disputes the propriety of the IAG Action, at the very least proceeding via litigation allows Sterigenics to receive pre-deprivation process, thus protecting its due process rights. But instead of proceeding through its already filed lawsuit,

IEPA and Kim have declared an emergency based on an ATSDR report, which was released *six months ago*, and the IRIS assessment, which was released *two years ago*. There is no emergency.

29. Through their Seal Order, IEPA and Kim are improperly seeking to circumvent both the regulatory and judicial processes. This improper action violates Sterigenics' due process rights.

WHEREFORE, Sterigenics respectfully requests: (1) entry of a temporary restraining order in its favor; (2) entry of a preliminary injunction in its favor; (3) entry of a permanent injunction in its favor; (4) entry of a judgment in its favor; (5) entry of an order requiring IEPA and Kim to lift the Seal Order and to cease enforcement of same; and (6) any other relief that this Court should deem just and appropriate.

COUNT II
Improper Use of Section 34(b) Authority

30. Sterigenics hereby incorporates Paragraphs 1–23 of this Complaint as if fully set forth herein.

31. Section 34(b) of the Illinois Environmental Protection Act gives IEPA the authority seal any “facility where the Agency finds that an emergency condition exists creating an immediate danger to public health or welfare or the environment” or “the Agency finds that an imminent and substantial endangerment to the public health or welfare or the environment exists.” 415 ILCS 5/34(b). If either of these conditions exist, “the Agency may seal any equipment, vehicle, vessel, aircraft, or other facility contributing to the emergency condition” or “to the imminent and substantial endangerment.” *Id.*

32. However, both USEPA and ATSDR have publicly acknowledged that the ATSDR report—the very report upon which the Seal Order relies—does not indicate an emergency or immediate health threat.

33. USEPA has also stated that it is premature to draw conclusions about long-term health risks from its data.² This is the same data cited to support the Seal Order.

34. Sterigenics disputes the validity of the conclusions reached in the ATSDR report, as well as the underlying IRIS assessment upon which it relies. Even ignoring this fact, the ATSDR report itself makes clear that the conclusions therein are intended to estimate the risk of *long-term* chronic health effects, based on an assumption that residents would be exposed 24 hours a day, 365 days a week, for 30 consecutive years, to concentrations of ethylene oxide that were purposefully selected to represent the *highest* maximum concentrations observed during the monitoring period. And even assuming all of this, the ATSDR authors themselves acknowledged that their report *did not characterize an immediate threat to health*. There is no “emergency” or “imminent and substantial endangerment.”

WHEREFORE, Sterigenics respectfully requests: (1) entry of a temporary restraining order in its favor; (2) entry of a preliminary injunction in its favor; (3) entry of a permanent injunction in its favor; (4) entry of a judgment in its favor; (5) entry of an order requiring IEPA and Kim to lift the Seal Order and to cease enforcement of same; and (6) any other relief that this Court should deem just and appropriate.

² EPA in Illinois: Sterigenics Willowbrook Facility – Latest Update: Update February 8, 2019, U.S. ENV'T'L PROTECTION AGENCY, <https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update#20181123> (last visited February 17, 2019).

Date: February 18, 2019

Respectfully submitted,

By: /s/ Gerard D. Kelly

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CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2019, I electronically filed the foregoing document with the clerk of the court for the Northern District of Illinois, Eastern Division, using the electronic case filing system of the court. The electronic case filing system sent a “Notice of EFiled” to the attorneys of record in this case.

/s/ Stephanie C. Stern

Stephanie C. Stern